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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,914	09/09/2003	Bret A. Ferree	BAF-14802/29	5106

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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/657,914	Applicant(s) FERREE, BRET A.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Specification

The abstract of the disclosure is objected to because on page 3, lines 11, 12, and 15, the meaning of "ADR" is not explained so that the meaning thereof is not clear. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 1 is objected to because of the following informalities: In claim 1, it is not clear what is meant by the term "natural" in "natural arthroplasty device" such that one cannot ascertain whether this limits the device to naturally occurring materials of the spinal region. Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 2-7, the term "components" renders the claim language scope indefinite because the base claim uses "one or more bio-resorbable components." For this reason, it is unclear whether the use of the plural "components" is supposed to limit the claim to more than one or not. When treating the claims on their merits, the Examiner will interpret the claims as claiming the range of "one or more components" since this is the broadest reasonable interpretation. In order to overcome

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this rejection, the Examiner suggests inserting "one or more" before "bio-resorbable" in each instance.

Regarding claim 9, claim 1 claims a "natural arthroplasty device", yet dependent claim 9 contradicts this by requiring that the arthroplasty device be "artificial." Since natural and artificial are opposites, the scope of the claim is considered clearly indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicholson et al (US 6,096,080). Nicholson anticipates the claim language where one or more bioabsorbable components are the implant (35) and barbs (36) of Nicholson (see Figures 5 and 6 as well as column 9, lines 24-52), and the prosthetic or natural arthroplasty device is implant (35) or the bone ingrowth material (see column 10, lines 1-14). The bio-resorbable material as claimed, is bone allograft disclosed by Nicholson.

Regarding claims 2 and 3 specifically, the component(s) can be a rod as claimed such as that shown by Nicholson as barb (36); see Figures 5 and 6.

Regarding claims 3-7, the claimed features are explicitly set forth or implicitly disclosed by Nicholson; see column 3, line 66 to column 4, line 26 and column 5, lines 26-65.

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With regard to claim 8, the Nicholson device can be made with bone allograft; see *supra*.

Response to Arguments

Applicant's arguments filed December 28, 2004 have been fully considered but they are not persuasive.

In response to the argument that "natural" is understood in the art, the Examiner disagrees and asserts that "natural" is used to mean anything from whole living tissue to material that have been physically altered (cut, commutated, compressed) or chemically altered (crosslinked, coated). Furthermore, the introduction of claim 9, where a natural arthroplasty device is an artificial intervertebral disc, highlights the confusion associated with this term. The Applicant's specification fails to make the distinction clear.

With regard to the Section 112 rejection traversal, the Examiner has suggested a change that will overcome this rejection.

With regard to the Section 102 rejection traversal, Applicant argues that Nicholson does not teach an arthroplasty device that is meant to move an articulate. However, the claims are viewed as requiring "a prosthetic" or alternatively, a "natural arthroplasty device." These two terms are considered almost mutually exclusive because "prosthetic" suggests something that is man-made not natural. Furthermore, Section 102 rejections only require a structure-to-structure comparison of the claimed invention to the prior art invention. Since Nicholson's device is a clearly a prosthetic

and arguably a natural arthroplasty device (because it can be made of allograft), the claim language is considered fully met.

Next, Applicant argues that the Nicholson device does not allow motion and mobility as required by claim 3. However, since only limited motion is required and this can be present "during" healing, the claim language is considered fully met.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending


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claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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